



## Prior Authorization Criteria

### **LYNPARZA® (OLAPARIB) PA CRITERIA:**

Lynparza is a poly (ADP-ribose) polymerase (PARP) inhibitor is FDA indicated for:

#### **Ovarian Cancer**

- **First-Line Maintenance Treatment of BRCA-mutated Advanced Ovarian Cancer**
  - For the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to first-line platinum based chemotherapy. Select patients with gBRCAm advanced epithelial ovarian, fallopian tube or primary peritoneal cancer for therapy based on an FDA-approved companion diagnostic for Lynparza
- **First-line Maintenance Treatment of HRD-positive Advanced Ovarian Cancer in Combination with Bevacizumab**
  - Lynparza is indicated in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:
    - a deleterious or suspected deleterious BRCA mutation, and/or
    - genomic instability
- **Maintenance Treatment of Recurrent Ovarian Cancer**
  - For the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy. ***(NOTE- this FDA indication will process via SMART PA)***
- **Advanced gBRCA-mutated Ovarian Cancer After 3 or More Lines of Chemotherapy**
  - For the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancers who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza

#### **Breast Cancer**

- **Germline BRCA-mutated HER2-negative Metastatic Breast Cancer**
  - For the treatment in patients with deleterious or suspected deleterious *gBRCAm*, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine

therapy or be considered inappropriate for endocrine treatment. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

### **Pancreatic Cancer**

- **First-Line Maintenance Treatment of Germline BRCA-mutated Metastatic Pancreatic Adenocarcinoma**
  - For the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza

Diagnosis: \_\_\_\_\_

ICD-10 code(s): \_\_\_\_\_

### **Initial Authorization: 6 months**

- Yes  No Prescribed by or in consultation with an oncologist; **AND**
- Yes  No Age of patient is within the age range as recommended by FDA label; **AND**
- **ONE** of the following:

### **Ovarian Cancer**

- **First-Line Maintenance Treatment of BRCA-mutated Advanced Ovarian Cancer**
  - Yes  No Physician attestation of deleterious or suspected deleterious BRCA mutations (*gBRCAm or sBRCAm*) as detected by FDA-approved test; **AND**
  - Yes  No Physician attestation of complete or partial response to first-line platinum based chemotherapy
- **First-line Maintenance Treatment of HRD-positive Advanced Ovarian Cancer in Combination with Bevacizumab**
  - Yes  No Physician attestation of homologous recombination deficiency (HRD)-positive status defined by either a deleterious or suspected deleterious BRCA mutation, and/or genomic instability; **AND**
  - Yes  No Physician attestation of complete or partial response to first-line platinum based chemotherapy

- **Advanced germline BRCA- mutated (gBRCAm) cancer (including epithelial, ovarian, fallopian tube or primary peritoneal cancer)**

Yes  No Physician attestation of deleterious or suspected deleterious BRCA mutations (*gBRCAm* or *sBRCAm*) as detected by FDA-approved test; **AND**

Yes  No Physician attestation of history of failure, contraindication, or intolerance to three or more prior lines of chemotherapy

- **Maintenance Treatment Recurrent Ovarian Cancer (will process through SMART PA, thus no “Yes or NO” answer is required)**

- Diagnosis of ovarian cancer, fallopian tube cancer or peritoneal cancer in past 2 years **AND**
- Claims history of a platinum-based chemotherapy agent in past 2 years

### **Breast Cancer**

- **Germline BRCA-mutated HER2-negative Metastatic Breast Cancer**

Yes  No Physician attestation of deleterious or suspected deleterious *gBRCAm*, as detected by an FDA-approved test, HER2-negative metastatic breast cancer that has been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting; **AND**

*Physician attestation for Metastatic Breast Cancer of one of the following:*

Yes  No Disease is hormone receptor (HR) negative and beneficiary has been previously treated with chemotherapy **OR**

Yes  No Disease is hormone receptor (HR) positive, with prior endocrine therapy, or treatment with endocrine therapy is inappropriate for the patient’s disease

### **Pancreatic Cancer**

- **First-Line Maintenance Treatment of Germline BRCA-mutated Metastatic Pancreatic Adenocarcinoma**

Yes  No Physician attestation of deleterious or suspected deleterious *gBRCAm*, metastatic pancreatic adenocarcinoma as detected by an FDA-approved test, **AND**

Yes  No Claims history of at least a first-line 16 week regimen of a platinum-based chemotherapy agent

**Reauthorization Criteria: 12 months**

**ALL of the following criteria must be met:**

- Yes  No Prescribed by or in consultation with an oncologist; **AND**
- Yes  No Condition does not show evidence of progressive disease while on Lynparza therapy (physician attestation); **AND**
- Yes  No Adherent with the medication as documented by claims history; **AND**
- Yes  No Individual has not developed any significant Level 4 adverse drug effects including Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML) or Pneumonitis

**Available Dosage Forms:**

Tablet: 150mg and 100 mg

- The 100 mg tablet is available for dose reduction.